REMARKS

Claims 1-4, 15-18, 22-25 and 30 are pending herein. Claims 1 and 3 have been amended for clarification purposes only. Claim 30 has been rewritten in independent form. Attached hereto as pages 11 and 12, pursuant to Rule 1.121(c)(1)(ii), is a marked-up version of the amended claims.

1. The Amendment filed February 22, 2002 was objected to under 35 USC §132 and claim 30 was rejected under §112, first paragraph in paragraphs 3 and 5, respectively, of the Office Action. The objection and rejection are respectfully traversed.

The PTO is alleging that the specification fails to define or provide any disclosure to support the "said base plate is non-permeable with respect to said capture solution" limitation recited in pending claim 30. As the following discussion demonstrates, however, a claim term, in a new or amended claim, does not have to be expressly recited in the specification to find enabling support.

There is no requirement to provide a literal description (i.e., using the same terms or *in haec verba*) of each claim term in order for the disclosure to satisfy the written description requirement (see MPEP 2163.02). According to the MPEP, newly added claim limitations can be supported in the specification through express, implicit or inherent disclosure in the specification (see MPEP 2163(I)(B)). Recent Federal Circuit case law supports this principle and makes clear that "the failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented." See *All Dental Prodx LLC v. Advantage Dental Products Inc.*, 64 USPQ2d 1945, 1948 (CA FC 2002) (citing *Eiselstein v. Frank*, 52 F.3d 1035, 34 USPQ2d 1467 (Fed. Cir. 1995).

The PTO's objection under 35 USC §132 and rejection under §112, first paragraph are each erroneous and should be withdrawn. It is clear that one skilled in the art would easily recognize that the present specification shows that the biochip that Applicants have invented is a biochip having a non-permeable base plate. See *All Dental Prodx LLC v. Advantage Dental Products Inc.*, 64 USPQ2d at 1948. That is, it is irrefutable that skilled artisans would understand that a non-permeable base plate is enabled by disclosure of a glass base

plate (see, for example, page 20, line 24 -- page 21, line 1 of the present specification).[1] Indeed, the PTO has already admitted that skilled artisans understand that a glass substrate is a non-permeable base plate (see Office Action page 7, lines 10 and 11).

In view of all of the foregoing, reconsideration and withdrawal of the objection to the February 22, 2002 Amendment under 35 USC §132 and rejection of claim 30 under 35 USC §112, first paragraph are respectfully requested.

2. The rejection of claims 1-4, 15-18, 22-25 and 30 under §112, second paragraph is noted, but deemed moot in view of rewritten claims 1 and 3 submitted above.

3. Claims 3, 4, 17, 18, 24, 25 and 30 were rejected under §102(e) over Audeh. This rejection is respectfully traversed.

Pending independent claim1 recites, among other things, that a plurality of spots of capture solutions having different spot sizes are supplied onto a base plate by means of an ink-jet system. Claim 1 has been amended to clarify that all of the capture solution spots have uniform detection sensitivity.

Pending independent claim 3 recites, among other things, that a plurality of spots of capture solutions are supplied onto a base plate by means of an ink-jet system. The concentration of the capture material in the capture solutions varies from spot to spot. Claim 3 has been amended to clarify that all of the capture solution spots have uniform detection sensitivity.

Applicants discovered that by supplying the capture solution spots onto the base plate using an ink-jet system it is possible to precisely deposit a plurality of sample spots onto the base plate to have a desired spot size. The degree of accuracy in spot size formation attributable to the claimed ink-jet process is not disclosed or suggested in the prior art (discussed below), or even attainable for that matter using prior art pin-head type arraying devices.

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[1] Again, in order to comply with the written description requirement of §112, first paragraph, the specification "need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the [filing] date the Applicant had invented what is now claimed." *Eiselstein v. Frank*, 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (citing *Vas-Cath*, 935 F.2d at 1562, 19 USPQ2d at 1115, and *In re Wertheim*, 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976)). It is clear that skilled artisans would know that, as of the filing date of the present application, Applicants had invented a biochip having a non-permeable base plate as is now claimed.

The claimed ink-jet process of supplying capture solution spots onto the base plate also yields deposited spots that have a more accurately and precisely controlled capture material concentration per sample spot. Accordingly, the claimed ink-jet process results in a base plate having sample spots deposited thereon that have an exact, desired amount of capture material per unit area of each sample spot. Such accuracy and precision are not attainable using prior art pin-head arraying devices (again, discussed below).

Before discussing the prior-art rejections of record, an example of the claimed ink-jet process will be explained. A first ink-jet sample spot that has a desired spot size and/or a desired capture material concentration is supplied onto the base plate and allowed to dry. A second ink-jet sample spot, which, for example, can have the same or a different spot size in relation to the first ink-jet sample spot and/or the same or a different capture material concentration, is then supplied on top of the dried first ink-jet sample spot. Due to the non-contact nature of the ink-jet process, the dried first ink-jet sample spot is not affected by the delivery of the second ink-jet supplied sample spot. Accordingly, every subsequently supplied ink-jet sample spot has an accurately and precisely controlled spot size and/or capture material concentration in relation to a desired parameter. As is explained below, this is not possible using the prior art pin-head sample spot delivery methods disclosed in the applied prior art references of record.

Audeh discloses that a probe sample solution is spotted onto a substrate using a 4-pin head arraying device (see page 4, paragraph [0043]). The pin heads are dipped into sample wells containing the probe sample solution to collect individual probe samples and spot the probe samples onto the substrate by physically tapping the end of each of the pin heads against the upper surface of the substrate. After each probe sample is spotted onto the substrate, each of the pin heads is washed with water and ethanol and air dried before the pin heads are re-inserted into the sample wells to collect another batch of probe sample solution to be subsequently supplied onto the substrate (see Audeh page 4, paragraph [0043]).

After the previously supplied probe sample solution spots have dried, another series of probe sample solution spots are subsequently placed onto the substrate using the washed pin heads in the arraying device. During the application of all subsequent probe sample spots, the pin heads contact the previously applied dried sample solution spots to deposit the

subsequently supplied probe sample spots on top of the previously supplied spots.

During this contact with the dried spots, some portion of the spot sticks to the pins. Skilled laboratory professionals understand that the washing and drying steps described in Audeh prevent dried particles of the previously supplied probe sample spots that have been picked up by the pin heads, which, again, contact all of the previously supplied spots, from contaminating the probe sample solution stored in the microtiter plate wells.

The PTO admits that Audeh does not disclose the use of an ink-jet system to supply the probe samples onto the substrate. Indeed, as discussed above, Audeh uses a pin-head arraying device for this purpose. The Office Action appears to indicate that the product-by-process ink-jet features recited in each of claims 1 and 3 have not been considered. The Office Action appears to take the position that these ink-jet product-by-process features can simply be ignored. Such action is clearly improper, as reflected by the body of law in existence regarding product-by-process claims recitation, e.g., as discussed in MPEP §2173.05(p). Proper consideration of the product-by-process recitation in pending claims 1 and 3 is respectfully requested.

As is properly stated, but apparently ignored in the Office Action, "...determination of patentability is based on the product itself"(e.g., see Office Action page 6). That is, if the process by which the product is formed yields a structurally distinct product, then the product-by-process claim limitation must be given weight in defining patentable subject matter over the prior art product. For the reasons explained below, it is respectfully submitted that the claimed ink-jet process provides a structurally distinct biochip over Audeh's probe sample array.

As explained above, Audeh's pin heads are required to contact all of the previously supplied probe samples and come into physical contact with the substrate every time a subsequent probe sample spot is deposited in the array. During this process, naturally, some of the previously applied dried probe sample is picked up by and remains on the pin head tips, and therefore becomes a contaminant, when the pin heads are retracted from the substrate. Again, as discussed above, Audeh discloses washing and drying steps, which skilled artisans would understand avoids this dried particle contamination problem.

While Audeh's pin-head spotting method may be capable of delivering a plurality of

spots that each have similar or different spot sizes to be within a ball-park range of one another, pin-head delivery systems do not, and cannot for that matter, provide an array of probe sample spots having sample spot size control that is within the same degree of accuracy and precision as that of the claimed ink-jet delivery process. This is so because, again, a portion of each of the previously applied dried probe sample spots is attached to and removed by the pin heads upon delivery of each subsequently formed probe sample spot. This effect is cumulative, which means that with every subsequently supplied probe sample spot, every previously supplied probe sample spot size changes.

Based on the above, it is clear that Audeh's pin-head method does not produce a probe sample array in which the sample spot sizes can be as accurately and precisely controlled as compared to the claimed ink-jet process. As such, Audeh does not disclose or suggest a probe sample array "wherein all of said spots have uniform detection sensitivity" within the degree of accuracy and precision as compared to the claimed ink-jet process, as recited in pending independent claim 1. Therefore, the claimed biochip is structurally distinct from Audeh's probe sample array.

Nor is Audeh's pin head spotting method capable of delivering probe sample spots that have a capture material density per unit area that is within the degree of accuracy and precision as that of the claimed ink-jet process. This is so for the same reasons explained above. Again, because a portion of each of the previously applied dried probe sample spots is attached to and removed by the by the pin heads upon application of the subsequently formed probe sample spots, the capture material concentration of each of the previously applied probe sample spots cannot be accurately and precisely controlled. Therefore, Audeh does not disclose or suggest a probe sample array "wherein all of said spots have uniform detection sensitivity" within the degree of accuracy and precision as compared to the claimed ink-jet process, as recited in pending independent claim 3. Therefore, the claimed biochip is structurally distinct from Audeh's probe sample array.

In view of all of the foregoing, reconsideration and withdrawal of the §102(e) rejection over Audeh are respectfully requested.

4. Claims 3, 4, 17, 18, 24, 25 and 30 were rejected under §102(e) over Mirzabekov. This rejection is respectfully traversed.

The PTO is apparently arguing that a peltier thermostated pin disclosed in Mirzabekov corresponds to an ink-jet system. Applicants respectfully submit that this statement is erroneous because skilled artisans clearly understand that the peltier thermostated pin is a pin-head type arraying device, the deficiencies of which have been discussed above. Therefore, for the reasons already discussed above with respect to the rejection based on Audeh et al., reconsideration and withdrawal of this rejection are respectfully requested.

5. Claims 3, 4, 17, 18, 24, 25 and 30 were rejected under §102(e) over Chenchik et al. This rejection is respectfully traversed.

The PTO admits that Chenchik does not teach that sample spots are supplied onto a base plate by means of an ink-jet system (see Office Action page 9). Indeed, Chenchik et al. disclose that probe sample solutions are pin-spotted onto the substrate surface using a Biomek 2000 (Beckmann) Robot (i.e., a pin-head type arraying device). Accordingly, for the same reasons already discussed above with respect to the rejection based on Audeh, reconsideration and withdrawal of this rejection are respectfully requested.

6. Claims 1, 2, 15, 16, 22 and 23 were rejected under §103(a) over Audeh in view of Dean et al. This rejection is respectfully traversed.

The deficiencies of Audeh have been discussed above and apply equally here. Dean is relied on in the Office Action for alleged disclosure that a linear relationship exists between spot concentration and spot size (see Office Action page 11). Therefore, it is clear that Dean does not cure the deficiencies of Audeh. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

7. Claims 1, 2, 15, 16, 22 and 23 were rejected under §103(a) over Mirzabekov in view of Dean et al. This rejection is respectfully traversed.

The deficiencies of Mirzabekov (which are the same deficiencies as Audeh) have been discussed above and apply equally to this rejection. For the same reasons explained above with respect to the §103(a) rejection over Audeh in view of Dean, Dean does not cure the deficient disclosure of Mirzabekov. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

8. Claims 1, 2, 15, 16, 22 and 23 were rejected under §103(a) over Chenchik et al. in view of Dean et al. This rejection is respectfully traversed.

The deficiencies of Chenchik have been discussed above (which are the same deficiencies as Audeh) and apply equally to this rejection. For the same reasons discussed above with respect to the §103(a) rejection over Audeh in view of Dean, Dean does not cure the deficient disclosure of Chenchik et al. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

If the Examiner believes that contact with Applicants' attorney would be advantageous toward the disposition of this case, the Examiner is herein requested to call Applicants' attorney at the phone number noted below.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,

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Date

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1. (Fourth Amended) A biochip comprising a large number of spots containing capture solutions arranged on a base plate, obtained by supplying, onto said base plate by means of an ink jet system, a plurality of types of said capture solutions each of which is adapted to specifically react with a specimen and provide information about a structure within the specimen, wherein:

a plurality of said spots, which have different spot sizes, are formed on said base plate, wherein ~~each~~all of said spots ~~has~~have uniform detection sensitivity.

3. (Fourth Amended) A biochip comprising a large number of spots of capture solutions containing a capture material therein arranged on a base plate, obtained by supplying, onto said base plate by means of an ink jet system, a plurality of types of said capture solutions each of which is adapted to specifically react with a specimen and provide information about a structure within the specimen, wherein:

a plurality of said spots are formed in which the concentration of the capture material in the capture solution varies from spot to spot, wherein ~~each~~all of said spots ~~has~~have uniform detection sensitivity.

30. (Amended) A biochip ~~according to claim 3, wherein~~comprising a large number of spots of capture solutions containing a capture material therein arranged on a base plate, obtained by supplying, onto said base plate by means of an ink jet system, a plurality of types of said capture solutions each of which is adapted to specifically react with a specimen and provide information about a structure within the specimen, wherein:

a plurality of said spots are formed in which the concentration of the capture material in the capture solution varies from spot to spot, wherein all of said spots have

uniform detection sensitivity and said base plate is non-permeable with respect to said capture solution.